REMARKS

Claims 1, 2 and 5-13 remain in the case. Claims 3, 4, 14-20 have been canceled. New claims 21-24 have been added. Support for these claims are found in the original claims in particular claims 16-20.

Claims 1, 3-6, 8-12, 14-16 have been rejected under 35 USC 102(b) as anticipated by Padgett (US 4,644,586). Applicants disagree.

As amended, the claims require that the second section of the bag contain sterilized contents and a seal formed between the first and section portion of the bag. Further the second section is in a condition of either slight vacuum or slight pressure to provide one with an indication of integrity.

The office action states at paragraph 9 that the reference is silent with respect to the use of any means for applying pressure or vacuum.

As the standard for anticipation is one of strict identity and "the reference must teach every aspect of the claimed invention either explicitly or inherently." (MPEP section 706.02IV, lines 6 and 7) and the cited reference has failed to teach the claimed element of molding or injection molding and the former and present office actions admit this is so, this reference is not and cannot be an anticipatory reference. As such, the rejection based on 35 USC 102(b) is respectfully requested to be withdrawn as it fails to provide a reference which contains all of the claimed elements of the present claims and therefore no basis for rejection under 35 USC 102 has been properly made.

Claims 1, 3-6, 8, 12, 14 and 15 have been rejected under 35 USC 102(b) as anticipated by Trewella et al (US 3,073,507). Applicants disagree.

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As amended, the claims require that the second section of the bag contain sterilized

contents and a seal formed between the first and section portion of the bag. Further the second

section is in a condition of either slight vacuum or slight pressure to provide one with an indication

of integrity.

The office action states at paragraph 9 that the reference is teaches the use of pressure

and vacuum during sterilization but the pressure in the bag is brought back to atmospheric at the

end of the sterilization and then the bag is sealed. Thus no pressure of vacuum is applied during

or after formation of the seal between the two sections.

As the standard for anticipation is one of strict identity and "the reference must teach every

aspect of the claimed invention either explicitly or inherently." (MPEP section 706.02IV, lines 6 and

7) and the cited reference has failed to teach the claimed element of molding or injection molding

and the former and present office actions admit this is so, this reference is not and cannot be an

anticipatory reference. As such, the rejection based on 35 USC 102(b) is respectfully requested to

be withdrawn as it fails to provide a reference which contains all of the claimed elements of the

present claims and therefore no basis for rejection under 35 USC 102 has been properly made.

Claims 2, 7, 13 have been rejected under 35 USC 103(a) over Trewella et al in view of

McDonald (US 6, 030,578). Applicants disagree.

As amended, the claims require that the second section of the bag contain sterilized

contents and a seal formed between the first and section portion of the bag. Further the second

section is in a condition of either slight vacuum or slight pressure to provide one with an indication

of integrity.

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The office action states at paragraph 9 that the reference is teaches the use of pressure and vacuum during sterilization but the pressure in the bag is brought back to atmospheric at the end of the sterilization and then the bag is sealed. Thus no pressure of vacuum is applied during or after formation of the seal between the two sections. McDonald doesn't overcome this defect as it is silent on the issue. The cited combination at best would use a bag and collar at atmospheric pressure.

The Patent and Trademark Office (PTO) bears the burden of initially establishing a prima facie case of obviousness. MPEP § 2142. MPEP § 2143 provides the standard required to establish a prima facie case of obviousness. "First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one or ordinary skill in the art, to modify the reference or to combine what the reference teaches. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references combined) must teach or suggest all the claim limitations."

The motivation to make the claimed invention and the reasonable expectation of success must both be <u>found in the prior art</u>, not the <u>applicant's disclosure</u>. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). The references must be considered as a whole and must suggest the desirability, and thus the obviousness of making the combination. *Hodosh v. Block Drug Col, Inc.*, 229 U.S.P.Q. 182, 187 n.5 (Fed. Cir. 1986); MPEP § 2141.

As no teaching, suggestion or motivation can be found in the cited references, the prima facie case of obviousness has not been established and the rejection should be withdrawn.

Claims 17-20 have been indicated as allowable except that they depended from a rejected independent claim and would be allowed if rewritten to include all the limitations of that claim. New claims 21-24 incorporate the elements of claim 16 and respectively of claims 17-20 and are therefore believed to be in condition for allowance.

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Applicant believes this reply is complete and conforms to the requirements of the Office Action. Reconsideration and allowance of the claims is respectfully requested.

Respectfully Submitted,

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 24, 2007.

Stacev Gross